LAXATIVE MAXIMUM STRENGTH- sennosides tablet WinCo Foods, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Winco 44-348

Active ingredient (in each tablet)

Sennosides USP, 25 mg

Purpose

Stimulant laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 6 to 12 hours

Warnings

Do not use

laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor.

Ask a doctor before use if you have

noticed a sudden change in bowel habits that persists over a period of 2 weeks.

Ask a doctor or pharmacist before use if you are

taking any other drug. Laxatives may affect how other drugs work. Take this product 2 or more hours before or after other drugs.

When using this product,

do not use for a period longer than 1 week.

Stop use and ask a doctor if

rectal bleeding or failure to have a bowel movement occur after use of a laxative. These may be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- swallow tablet(s) with a glass of water
- swallow tablet(s) whole; do not crush, break, or chew

adults and children	2 tablets once or
12 years and over	twice daily
children 6 to under	1 tablet once or
12 years	twice daily
children under 6 years	ask a doctor

Other information

- each tablet contains: calcium 40 mg, magnesium 5 mg
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- see end flap for expiration date and lot number
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

acacia, calcium carbonate, carnauba wax, corn starch, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, iron oxide black, magnesium stearate, methylparaben, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, propylene glycol, propylparaben, shellac glaze, silicon dioxide, sodium benzoate, sodium lauryl sulfate, sucrose, talc, titanium dioxide

Ouestions?

Call **1-800-824-1706** Monday - Friday 9am - 4pm MST

Principal Display Panel

*Compare to the active ingredient in EX•LAX® Maximum Strength

WinCo®

FOODS

MAXIMUM STRENGTH

Laxative

SENNOSIDES USP 25 mg/ STIMULANT LAXATIVE

Gentle, Overnight Relief

24

Tablets

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704

*This product is not manufactured or distributed by GSK Consumer Healthcare S.A., distributor of $EX \cdot LAX^{\$}$ Maximum Strength.

100% SATISFACTION GUARANTEE

Comments & Questions? 800-824-1706

50844 REV0419C34808 WF1911

lauryl sulfate, sucrose, talc, titanium dioxide shelke glaze, silicon dioxide, sodium benzoate, sodium alcohol, povidone, propylene glycol, propylparaben, microcrystalline cellulose, polyethylene glycol, polyvinyl plack, magnesium stearate, methylparaben, קבות וועסט) **בוכון החות** (coununed)

carnauba wax, оотп starch, dibasic calcium phosphate dihydrate, HD &C blue #1 aluminum lake, iron oxide **Inactive ingredients** acacia, calcium carbonate,

12,-30,C (26,-86,E)

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(panunuoo) **siae4 bini**(l

■ see end flap for expiration date and lot number IS OPENED OR BLISTER IS TORN OR BROKEN ■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE ■ each tablet contains: calcium 40 mg, magnesium 5 mg Other information

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twice daily	12 years
1 tablet once or	children 6 to under
twice daily	12 years and over
2 tablets once or	adults and children

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These may be signs of a serious condition. to have a bowel movement occur after use of a laxative. Stop use and ask a doctor if rectal bleeding or failure

Drug Facts (continued)

than 1 week When using this product, do not use for a period longer

before or after other drugs.

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50844 REV0419C34808 WF1911

100% SATISFACTION GUARANTEE Comments & Questions? 800-824-1706

change in bowel habits that persists over a period of 2 Ask a doctor before use if you have noticed a sudden

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Do not use laxative products when abdominal pain, Warnings

■ generally produces bowel movement in 6 to 12 hours USes relieves occasional constipation (irregularity)

evitexal trallumite. Sennosides USP, 25 mg.

INFORMATION

FOR COMPLETE PRODUCT KEEP OUTER PACKAGE

Purpose

(in each tablet) Active ingredient

Drug Facts

Drug Facts (continued)

Questions? Call **1-800-824-1706** Monday - Friday

9am - 4pm MST

B-2150-348-08 REV0419C34808

Lot & Exp. Date No Print/No Varnish

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BUSTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

WinCo

MAXIMUM STRENGTH Laxative



*Compare to the active ingredient in EX•LAX® Maximum Strength

Gentle, Overnight Relief

WinCo FOODS

MAXIMUM STRENGTH Laxative

SENNOSIDES USP 25 mg/ STIMULANT LAXATIVE

Winco 44-348

sennosides tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67091-217

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CENNOCIDES (LINII, SEVDEMOLIV) (CENNOCIDES LINII, SEVDEMOLIV)	CENINOCIDEC	25 mg

SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX) SENNOSIDES 25 mg

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
SHELLAC (UNII: 46N107B710)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	

Product	Characte	. wickies
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SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)

Color	blue	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44;348
Contains			

	ka		

Item Code Package Description Marketing Start Date Date

1	NDC:67091- 217-24	2 in 1 CARTON	01/02/2003	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information						
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date						
part334	01/02/2003					
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date				

Labeler - WinCo Foods, LLC (056098817)

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		038154464	pack(67091-217)		

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(67091-217)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(67091-217)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(67091-217)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(67091-217)

Revised: 3/2021 WinCo Foods, LLC